5. Traditional 510(k) Summary

Name of Submitter: ICU Medical, Incorporated
4455 Atherton Drive
Salt Lake City, Utah 84123

JUN – 5 2007

Manufacturer and Establishment Registration Number:

Manufacturer:	***Sterilization Site:***
ICU Medical (Utah), Inc 4455 Atherton Drive Salt Lake City, Utah 84123 Site Registration Number: 1713468	ICU Medical de Mexico, S.A. de C.V. Avenida Cuarzo #250 Colonia Rancho Santa clara El Valle de Maneadero Ensenada, B.Cfa., MEXICO 22790 Site Registration Number: 9617594
-- OR --	
ICU Medical de Mexico, S.A. de C.V. Avenida Cuarzo #250 Colonia Rancho Santa clara El Valle de Maneadero Ensenada, B.Cfa., MEXICO 22790 Site Registration Number: 9617594	Beam-One LLC 9020 Activity Rd., suite D San Diego, California 92126 Site Registration Number: 2030598

Proprietary or Trade Name of Proposed Device: Genie™

Common Name: Vial Access Device

Device Classification: Class II

Product Code: FMF, MEG

Performance Standards:

There is a performance standard for this Classification Product Code FMF (Primary) and MEG (Secondary) under Section 514 of the Food, Drug and Cosmetic Act for Syringe, Piston, Needleless. This device is an accessory to a Piston Syringe, and is regulated within 21 CFR 880.5860.

Intended Use / Indications for Use:

The Genie is an accessory to a syringe that provides a mean of sterile access to drug vials without the use of conventional needles (needleless). These devices are designed to improve user safety by reducing the exposure that health-care workers are subjected to regarding aerosolizing hazards and accidental needle sticks.

Proposed Device Description:

The Genie™ is intended for use as an accessory to an I.V. set. The Genie™ is used to adapt a standard medication vial for needle free access and to maintain the sterile system. In addition, the Genie™ automatically equalizes vial pressure as fluids are withdrawn and therefore reduces the risk for health-care workers for exposure to potentially hazardous drug aerosols, spills or needle sticks that can occur during the preparation, administration and dispensing process.

Summary of Substantial Equivalence:

Similarities:

1. The predicate and subject devices have the same or similar intended use.
2. The predicate and subject devices have the same or similar indications for use.
3. The predicate and subject devices contain the components made from materials tested and qualified per ISO 10993-1:2003.

Differences:

1. The subject device will use an internal balloon for pressure equalization, while the predicate device (K001368) uses an external balloon or a filtered vent.

Statement of Safety and Effectiveness:

The Genie™ vial access device has been tested post sterilization and passed all acceptance criteria. The Genie™ vial access device meets the functional claims and intended use as described in the product labeling and is safe and effective in terms of substantial equivalence as the predicate devices described in this document.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Martin Maier
Senior Quality Assurance
ICU Medical, Incorporated
4455 Atherton Drive
Salt Lake City, Utah 84123

JUN - 5 2007

Re: K070633
Trade/Device Name: Genie™
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston Syringe
Regulatory Class: II
Product Code: FMF
Dated: March 6, 2007
Received: March 7, 2007

Dear Mr. Maier:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

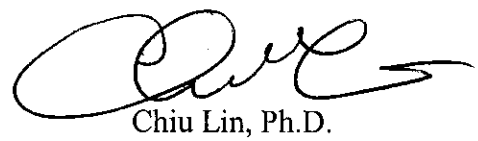
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K070633**

Device Name: **Genie™**

Indications for Use:

The Genie is an accessory to a syringe that provides a mean of sterile access to drug vials without the use of conventional needles (needleless). These devices are designed to improve user safety by reducing the exposure that health-care workers are subjected to regarding aerosolizing hazards and accidental needle sticks.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K070633